

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Gentz et al

Docket No.: PF402C1D1

Application No.: Not Yet Assigned

Group Art Unit: N/A

Filed: Herewith

Examiner: Not Yet Assigned

For: Keratinocyte Growth Factor-2 Formulations

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 to inform the Patent and Trademark Office of all references coming to the attention of each individual associated with the filing or prosecution of the subject application, which are or may be material to the patentability of a claim of the subject application, Attorneys for Applicants hereby direct the Examiner's attention to references AA-EP listed on the attached Form PTO/SB/08.

Copies of references AA-EP were submitted by Applicants or cited by the Examiner in connection with U. S. Patent Application Serial No. 09/853,666, filed May 14, 2001, to which the instant application claims priority under 35 U.S.C. § 120. Pursuant to 37 C.F.R. § 1.98(d), the Examiner is directed to the file of U. S. Patent Application Serial No. 09/461,419 for copies of references AA-EP.

The above information is presented so that the Patent and Trademark Office can determine any materiality thereof to the claimed invention. See 37 CFR § 1.104(a) concerning the PTO duty to consider and use any such information. It is respectfully requested that the information be considered during the prosecution of this application.

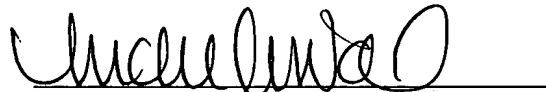
Identification of the listed references is not to be construed as an admission of any individual associated with the filing or prosecution of the subject application that such references are available as "prior art" against the subject application. Furthermore, Applicants do not waive any rights to appropriate action to establish patentability over any of the listed documents should they be applied as references against the claims of the subject application.

Applicants respectfully request that the Examiner review the listed references and that the references be made of record in the file history of the application.

This Information Disclosure Statement accompanies the new patent application submitted herewith. Accordingly, no fee is believed due in connection herewith. However, should the Patent Office determine otherwise, please charge the required fee to Human Genome Sciences, Inc., deposit account no. 08-3425.

Respectfully submitted,

Dated: October 30, 2003



Michele M. Wales

Registration No.: 43,975
HUMAN GENOME SCIENCES, INC..
9410 Key West Avenue
Rockville, Maryland 20850
(301) 610-5772

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application Number	Not Yet Assigned
				Filing Date	Herewith
				First Named Inventor	Reiner L. Gentz
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	1	of	8	Attorney Docket Number	PF402C1D1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	5,194,596	03/16/1993	Tischer <i>et al.</i>	
	AB	5,350,836	09/27/1994	Kopchick <i>et al.</i>	
	AC	5,580,856	12/03/1996	Prestrelski <i>et al.</i>	
	AD	5,677,278	10/14/1997	Gospodarowicz <i>et al.</i>	
	AE	5,703,047	12/30/1997	Wilson	
	AF	5,731,170	03/24/1998	Rubin <i>et al.</i>	
	AG	5,773,252	06/30/1998	Greene <i>et al.</i>	
	AH	5,773,586	06/30/1998	Gospodarowicz <i>et al.</i>	
	AI	5,814,605	09/29/1998	Pierce <i>et al.</i>	
	AJ	5,824,643	10/20/1998	Pierce <i>et al.</i>	
	AK	5,843,883	12/01/1998	Gospodarowicz <i>et al.</i>	
	AL	5,863,767	01/26/1999	Gospodarowicz <i>et al.</i>	
	AM	6,077,692	06/20/2000	Ruben <i>et al.</i>	
	AN	6,238,888 B1	05/29/2001	Gentz <i>et al.</i>	

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶	
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)					
	AO	WO 90/08771	08/09/1990	Rubin et al.			
	AP	WO 92/14480	09/03/1992	Amgen Inc.			
	AQ	WO 92/22304	12/23/1992	Amgen Inc.			
	AR	WO 93/21908	11/11/1993	Amgen Inc.			
	AS	EP 0 619 370 A1	10/12/1994	Amgen Inc.			
	AT	WO 94/22427	10/13/1994	Amgen Inc.			
	AU	WO 94/23032	10/13/1994	Amgen Inc.			
	AV	WO 95/01434	01/12/1995	Chiron Inc.			
	AW	WO 95/03831	02/09/1995	Prizm Pharmaceuticals, Inc.			

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant

¹ Applicant's unique citation designation number (optional). ² See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	AX	WO 95/24928	09/21/1995	Sumitomo Pharmaceuticals Co., Ltd.		
	AY	WO 95/24928 A3	09/21/1995	Sumitomo Pharmaceuticals Co., Ltd.		
	AZ	JP 7-345689	12/07/1995	Sumitomo Pharmaceuticals Co., Ltd.		
	BA	JP 8-103240	03/28/1996	Sumitomo Pharmaceuticals Co., Ltd.		
	BB	WO 96/11949	04/25/1996	Amgen Inc.		
	BC	WO 96/11950	04/25/1996	Amgen Inc.		
	BD	WO 96/11951	04/25/1996	Amgen Inc.		
	BE	WO 96/11952	04/25/1996	Amgen Inc.		
	BF	JP 8-214378	07/24/1996	Sumitomo Pharmaceuticals Co., Ltd.		
	BG	WO 96/22369	07/25/1996	Amgen Inc.		
	BH	WO 96/25422	08/22/1996	Human Genome Sciences, Inc.		
	BI	WO 97/20929	12/06/1997	Sumitomo Pharmaceuticals Co., Ltd.		
	BJ	WO 98/06844	02/19/1998	Human Genome Sciences, Inc.		
	BK	WO 98/16243	04/23/1998	Amgen, Inc.		
	BL	WO 98/16642	04/23/1998	Amgen, Inc.		
	BM	GB 2 321 852 A	08/12/1998	Rohto Pharmaceutical Co. Ltd.		
	BN	JP 10-330283	12/15/1998	Sumitomo Seiyaku Corp. Ltd.		
	BO	JP 10-330284	12/15/1998	Sumitomo Seiyaku Corp. Ltd.		
	BP	JP 10-330285	12/15/1998	Sumitomo Seiyaku Corp. Ltd.		
	BQ	WO 99/32135	07/01/1999	Human Genome Sciences, Inc.		
	BR	WO 99/41282	08/19/1999	Human Genome Sciences, Inc.		
	BS	WO 00/72872	12/07/2000	Human Genome Sciences, Inc.		

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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	BT	WO 01/02433	01/11/2001	Human Genome Sciences, Inc.		
	BU	EP 0 619 115	10/12/1994	Amgen, Inc.		
	BV	EP 0 518 697	12/16/1992	Amgen, Inc.		

OTHER - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	BW	BOWIE, J.U., <i>et al.</i> , "Deciphering the Message in Protein Sequences: Tolerance to Amino Acid Substitutions," <i>Science</i> 247:1306-1310, American Association for the Advancement of Science (1990).	
	BX	CHEN <i>et al.</i> "Stabilization of recombinant human keratinocyte growth factor by osmolytes and salts", <i>J. Pharm. Sciences</i> 85(4):419-422 (1996).	
	BY	CHEN <i>et al.</i> "Aggregation pathway of recombinant human keratinocyte growth factor and its stabilization", <i>Pharmaceutical Research</i> 11(11):1581-1587 (1994).	
	BZ	FINCH, P.W., <i>et al.</i> , "Human KGF Is FGF-Related with Properties of a Paracrine Effector of Epithelial Cell Growth," <i>Science</i> 245:752-755, American Association for the Advancement of Science (1989).	
	CA	HARTUNG, H., <i>et al.</i> , "Murine FGF-12 and FGF-13: expression in embryonic nervous system, connective tissue and heart," <i>Mech. Dev.</i> 64:31-39, Elsevier Science Ireland Ltd. (1997).	
	CB	HARTUNG, H., <i>et al.</i> , "Assignment ^a of <i>Fgf12</i> to mouse chromosome bands 16B1→B3 in situ hybridization," <i>Cytogenet. Cell Genet.</i> 76:185-186, Karger A.G. (1997).	
	CC	JIMENEZ, P., <i>et al.</i> , "Effect of Topical Keratinocyte Growth Factor-2 on Wound Healing In A Glucocorticoid-Impaired Model," <i>J. Cutan. Pathol.</i> 24:105, Munksgaard (1997).	

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OTHER – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	CD	JIMENEZ, P.A., <i>et al.</i> , "Effect of Keratinocyte Growth Factor-2 on Cell Proliferation <i>In Vivo</i> ," <i>FASEB J.</i> 11:A523, Abstract No. 3025, Federation of American Societies for Experimental Biology (1997).	
	CE	JIMENEZ, P.A. and Rampy, M.A., "Keratinocyte Growth Factor-2 Accelerates Wound Healing in Incisional Wounds," <i>J. Surg. Res.</i> 81:238-242, Academic Press, Inc. (1999).	
	CF	KELLEY, M.J., <i>et al.</i> , "Emergence of the keratinocyte growth factor multigene family during the great ape radiation," <i>Proc. Natl. Acad. Sci. USA</i> 89:9287-9291, National Academy of Sciences (1992).	
	CF	MASON, I.J., <i>et al.</i> , "FGF-7 (keratinocyte growth factor) expression during mouse development suggests roles in myogenesis, forebrain regionalisation and epithelial-mesenchymal interactions," <i>Mech. Dev.</i> 45:15-30, Elsevier Science Ireland Ltd. (1994).	
	CG	MIYAMOTO, M., <i>et al.</i> , "Molecular Cloning of a Novel Cytokine cDNA Encoding the Ninth Member of the Fibroblast Growth Factor Family, Which Has a Unique Secretion Property," <i>Mol. Cell. Biol.</i> 13:4251-4259, American Society for Microbiology (1993).	
	CH	NGO, J.T., <i>et al.</i> , "Computational Complexity, Protein Structure Prediction, and the Levinthal Paradox," in: <i>The Protein Folding Problem and Tertiary Structure Prediction</i> , Merz, Jr., K. and Le Grand, S., eds., Birkhauser, Boston, Massachusetts, pp. 491-495 (1994).	
	CI	ROBSON, B. and Garnier, J., "Modern ideas and notations relating to primary structure," in: <i>Introduction to Proteins and Protein Engineering</i> , Robson, B. and Garnier, J., eds., Elsevier Science, Amsterdam, The Netherlands, p.41 (1986).	
	CJ	RON, D., <i>et al.</i> , "Expression of Biologically Active Recombinant Keratinocyte Growth Factor," <i>J. Biol. Chem.</i> 268:2984-2988, American Society for Biochemistry and Molecular Biology, Inc. (1993).	
	CK	WELLS, J.A., "Additivity of Mutational Effects in Proteins," <i>Biochem.</i> 29:8509-8517, American Chemical Society, (1990).	

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				Examiner Name	Not Yet Assigned
Sheet	5	of	8	Attorney Docket Number	PF402C1D1

CL	SCOPES, R.K. "Protein Purification: Principles and Practice" (3 rd ed.) New York: Springer-Verlag (1994).	
CM	YAMASAKI, M., <i>et al.</i> , "Structure and Expression of the Rat mRNA Encoding a Novel Member of the Fibroblast Growth Factor Family," <i>J. Biol. Chem.</i> 271:15918-15921, American Society for Biochemistry and Molecular Biology, Inc. (1996).	
CN	YAN, G., <i>et al.</i> , "Sequence of Rat Keratinocyte Growth Factor (Heparin-Binding Growth Factor Type 7)," <i>In Vitro Cell. Dev. Biol.</i> 27A:437-438, Tissue Culture Association (1991).	
CO	NCBI Entrez, GenBank Report with Revision History, Accession No. M79878, McCombie, W.R. <i>et al.</i> , National Center for Biotechnology Information (June 1992).	
CP	NCBI Entrez, GenBank Report with Revision History, Accession No. T52063, Hillier, L. <i>et al.</i> , National Center for Biotechnology Information (February 1995).	
CQ	NCBI Entrez, GenBank Report with Revision History, Accession No. D46201, Sasaki, T. <i>et al.</i> , National Center for Biotechnology Information (August 1995).	
CR	NCBI Entrez, GenBank Report with Revision History, Accession No. D46420, Sasaki, T. <i>et al.</i> , National Center for Biotechnology Information (August 1995).	
CS	NCBI Entrez, GenBank Report with Revision History, Accession No. D54216, Fujiwara, T. <i>et al.</i> , National Center for Biotechnology Information (September 1995).	
CT	NCBI Entrez, GenBank Report with Revision History, Accession No. D68729, Kohara, Y. <i>et al.</i> , National Center for Biotechnology Information (December 1995).	
CU	NCBI Entrez, GenBank Report with Revision History, Accession No. D69248, Kohara, Y. <i>et al.</i> , National Center for Biotechnology Information (December 1995).	
CV	NCBI Entrez, GenBank Report with Revision History, Accession No. D65627, Kohara, Y. <i>et al.</i> , National Center for Biotechnology Information (December 1995).	
CW	NCBI Entrez, GenBank Report with Revision History, Accession No. D66221, Kohara, Y. <i>et al.</i> , National Center for Biotechnology Information (December 1995).	
CX	NCBI Entrez, GenBank Report with Revision History, Accession No. C02000, Okubo, K., National Center for Biotechnology Information (July 1996).	
CY	NCBI Entrez, GenBank Report with Revision History, Accession No. W29377, Marra, M. <i>et al.</i> , National Center for Biotechnology Information (September 1996).	
CZ	NCBI Entrez, GenBank Report with Revision History, Accession No. W32720, Hillier, L. <i>et al.</i> , National Center for Biotechnology Information (October 1996).	

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	DA	NCBI Entrez, GenBank Report with Revision History, Accession No. W60824, Hillier, L. <i>et al.</i> , National Center for Biotechnology Information (October 1996).	
	DB	NCBI Entrez, GenBank Report with Revision History, Accession No. T70682, Shen, B. <i>et al.</i> , National Center for Biotechnology Information (October 1996).	
	DC	NCBI Entrez, GenBank Report with Revision History, Accession No. AA094753, Liew, C.C., National Center for Biotechnology Information (October 1996).	
	DD	NCBI Entrez, GenBank Report with Revision History, Accession No. AA133331, Hillier, L. <i>et al.</i> , National Center for Biotechnology Information (November 1996).	
	DE	NCBI Entrez, GenBank Report with Revision History, Accession No. AA190058, Marra, M. <i>et al.</i> , National Center for Biotechnology Information (January 1997).	
	DF	NCBI Entrez, GenBank Report with Revision History, Accession No. AA018953, Hillier, L. <i>et al.</i> , National Center for Biotechnology Information (January 1997).	
	DG	NCBI Entrez, GenBank Report with Revision History, Accession No. AA240978, Marra, M. <i>et al.</i> , National Center for Biotechnology Information (March 1997).	
	DH	NCBI Entrez, GenBank Report with Revision History, Accession No. AA289560, Marra, M. <i>et al.</i> , National Center for Biotechnology Information (April 1997).	
	DI	NCBI Entrez, GenBank Report with Revision History, Accession No. AA296993, Adams, M.D. <i>et al.</i> , National Center for Biotechnology Information (April 1997).	
	DJ	NCBI Entrez, GenBank Report with Revision History, Accession No. AA298937, Adams, M.D. <i>et al.</i> , National Center for Biotechnology Information (April 1997).	
	DK	NCBI Entrez, GenBank Report with Revision History, Accession No. AA312184, Adams, M.D. <i>et al.</i> , National Center for Biotechnology Information (April 1997).	
	DL	NCBI Entrez, GenBank Report with Revision History, Accession No. AA312483, Adams, M.D. <i>et al.</i> , National Center for Biotechnology Information (April 1997).	
	DM	NCBI Entrez, GenBank Report with Revision History, Accession No. AA356781, Adams, M.D. <i>et al.</i> , National Center for Biotechnology Information (April 1997).	
	DN	NCBI Entrez, GenBank Report with Revision History, Accession No. AA412789, Marra, M. <i>et al.</i> , National Center for Biotechnology Information (May 1997).	
	DO	NCBI Entrez, GenBank Report, Accession No. U67918, Jimenez, P.A. <i>et al.</i> , National Center for Biotechnology Information (July 1997).	

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	DP	NCBI Entrez, GenBank Report with Revision History, Accession No. AA472256, Marra, M. <i>et al.</i> , National Center for Biotechnology Information (June 1997).	
	DQ	NCBI Entrez, GenBank Report with Revision History, Accession No. C38464, Kohara, Y. <i>et al.</i> , National Center for Biotechnology Information (September 1997).	
	DR	NCBI Entrez, GenBank Report with Revision History, Accession No. C56505, Kohara, Y. <i>et al.</i> , National Center for Biotechnology Information (September 1997).	
	DS	NCBI Entrez, GenBank Report with Revision History, Accession No. C57074, Kohara, Y. <i>et al.</i> , National Center for Biotechnology Information (September 1997).	
	DT	NCBI Entrez, GenBank Report with Revision History, Accession No. C58558, Kohara, Y. <i>et al.</i> , National Center for Biotechnology Information (September 1997).	
	DU	NCBI Entrez, GenBank Report with Revision History, Accession No. C58846, Kohara, Y. <i>et al.</i> , National Center for Biotechnology Information (September 1997).	
	DV	NCBI Entrez, GenBank Report with Revision History, Accession No. C59317, Kohara, Y. <i>et al.</i> , National Center for Biotechnology Information (September 1997).	
	DW	NCBI Entrez, GenBank Report with Revision History, Accession No. C59311, Kohara, Y. <i>et al.</i> , National Center for Biotechnology Information (September 1997).	
	DX	NCBI Entrez, GenBank Report with Revision History, Accession No. AA605609, Clark, M. <i>et al.</i> , National Center for Biotechnology Information (September 1997).	
	DY	NCBI Entrez, GenBank Report with Revision History, Accession No. AA621871, NCI-CGAP, National Center for Biotechnology Information (October 1997).	
	DZ	NCBI Entrez, GenBank Report with Revision History, Accession No. AA621888, NCI-CGAP, National Center for Biotechnology Information (October 1997).	
	EA	NCBI Entrez, GenBank Report with Revision History, Accession No. AA675470, Marra, M. <i>et al.</i> , National Center for Biotechnology Information (November 1997).	
	EB	NCBI Entrez, GenBank Report with Revision History, Accession No. AA675519, Marra, M. <i>et al.</i> , National Center for Biotechnology Information (November 1997).	
	EC	NCBI Entrez, GenBank Report with Revision History, Accession No. AA838994, Marra, M. <i>et al.</i> , National Center for Biotechnology Information (February 1998).	
	ED	NCBI Entrez, GenBank Report with Revision History, Accession No. H35048, Lee, N.H. <i>et al.</i> , National Center for Biotechnology Information (April 1998).	
	EE	NCBI Entrez, GenBank Report with Revision History, Accession No. AA906051, NCI-CGAP, National Center for Biotechnology Information (May 1998).	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant

¹ Applicant's unique citation designation number (optional). ² See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
				Application Number	Not Yet Assigned
				Filing Date	Herewith
				First Named Inventor	Reiner L. Gentz
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	8	of	8	Attorney Docket Number	PF402C1D1

	EF	NCBI Entrez, GenBank Report with Revision History, Accession No. C78836, Ko, M.S.H. <i>et al.</i> , National Center for Biotechnology Information (June 1998).	
	EG	Dialog File 351, Accession No. 12329483, Derwent WPI English language abstract for JP 10-330283.	
	EH	Dialog File 351, Accession No. 12294894, Derwent WPI English language abstract for JP 10-330284.	
	EI	Dialog File 351, Accession No. 12303256, Derwent WPI English language abstract for JP 10-330285.	
	EJ	English language translation of WO 97/20929 (Document BH).	
	EK	English language translation of JP 7-345689 (Document AY).	
	EL	English language translation of JP 8-103240 (Document AZ).	
	EM	English language translation of JP 8-214378 (Document BE).	
	EN	English language translation of JP 10-330283 (Document BM).	
	EO	English language translation of JP 10-330284 (Document BN).	
	EP	English language translation of JP 10-330285(Document BO).	

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¹ Applicant's unique citation designation number (optional). ² See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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